# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

)
) C.A. No. 4:09-CV-11340 (FDS)
)
) HEARING REQUESTED
) Date/Time: January 23, 2013/1:30 p.m
)
)
) Leave to File Granted on Jan. 10, 2013
) [D.I. 531]
)
)
)

ABBOTT'S REPLY MEMORANDUM IN SUPPORT OF ITS MOTION FOR A NEW TRIAL

# **TABLE OF CONTENTS**

		Page
I.	INTR	ODUCTION1
II.	ARGU	JMENT1
	A.	The Jury Verdict is Not Supported by the Clear Weight of the Evidence1
	B.	There Was Improper Introduction of Irrelevant Evidence and Argument Concerning Stelara
	C.	Abbott Was Erroneously Precluded From Examining Witnesses Concerning the Prosecution of the Patents-In-Suit
		1. The Record Left an Incorrect Impression Regarding the Prosecution of the Patents-In-Suit
		2. Abbott Was Improperly Foreclosed From Presenting Evidence Regarding the Non-Interference Prosecution History
	D.	The Court's <i>i4i</i> Instruction Was Erroneous
	E.	The Near Simultaneous Invention Instruction Was Improper
	F.	The Court Erred in Admitting Post-Filing Evidence Related to Obviousness14
III.	CONC	CLUSION15

# TABLE OF AUTHORITIES

CASES	Page(s)
Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313 (Fed. Cir. 2003)	3
Amphenol T&M Antennas, Inc. v. Centurion Int'l, Inc., No. 00 C4298, 2002 U.S. Dist. LEXIS 822 (N.D. Ill. Jan. 17, 200)	2)7
Applied Medical Resources Corp. v. U.S. Surgical Corp., 147 F.3d 1374 (Fed. Cir. 1998)	7, 8
Callaway Golf Co. v. Acushnet Co., 576 F.3d 1331 (Fed. Cir. 2009)	7
CardioVention, Inc. v. Medtronic, Inc., 483 F. Supp. 2d 830 (D. Minn. 2007)	7
Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC, 618 F.3d 1294 (Fed. Cir. 2010)	13
Gomez v. Rivera Rodriguez, 344 F.3d 103 (1st Cir. 2003)	1
Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986)	13
IA Labs CA, LLC v. Nintendo Co., 857 F. Supp. 2d 550 (D. Md. 2012)	7
In re Farrenkopf, 713 F.2d 714 (Fed. Cir. 1983)	13
In re Roemer, 258 F.3d 1303 (Fed. Cir. 2001)	14
<i>In re Wallach</i> , 378 F.3d 1330 (Fed. Cir. 2004)	2
Jennings v. Jones, 587 F.3d 430 (1st Cir. 2009)	1
Keeler v. Hewitt, 697 F.2d 8 (1st Cir. 1982)	1

# Case 4:09-cv-11340-FDS Document 534 Filed 01/11/13 Page 4 of 22

Lind v. Schenley Industries, 278 F.2d 79 (3d Cir. 1960)	1
Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452 (Fed. Cir. 1984)	12
Minemyer v. B-Roc Representatives, Inc., No. 07 C 1763, 2012 U.S. Dist. LEXIS 12808 (N.D. Ill. Feb. 2, 2012)10	), 11
Mycogen Corp. v. Monsanto Co., No. 1:04-cv-00573, 2005 U.S. Dist. LEXIS 19375 (S.D. Ind. Aug. 11, 2005)	10
Regents of the Univ. of California v. Dako North America, Inc., No. 05-3955, 2009 WL 1083446 (N.D. Cal. Apr. 22, 2009)	2

### I. INTRODUCTION

Centocor's attempt to dismiss Abbott's arguments as mere disagreements with the jury's verdict fails to adequately address the prejudicial errors that occurred, which affected the outcome of the trial. And while Centocor concludes that a new trial is not warranted based on its piecemeal arguments as to each individual error, it wholly fails to assess the aggregate effect of these errors on the outcome of trial, as is required under the law. *Gomez v. Rivera Rodriguez*, 344 F.3d 103, 118 (1st Cir. 2003). When the trial record is viewed as a whole, Abbott's Motion For a New Trial should be granted, in the alternative to Abbott's Renewed Motion for Judgment as a Matter of Law.

### II. ARGUMENT

## A. The Jury Verdict is Not Supported by the Clear Weight of the Evidence

Centocor's Opp. to Abbott's Mot. for a New Trial ("Centocor Opp.") at 3.) However, when the verdict is "scrutinized more closely" due to the complicated subject matter involved, it is evident that no reasonable jury could have returned a verdict of invalidity under the controlling law and the facts presented. *Lind v. Schenley Indus.*, 278 F.2d 79, 90-91 (3d Cir. 1960), *cited in Keeler v. Hewitt*, 697 F.2d 8, 12 (1st Cir. 1982). Additionally, the Court's "power to grant a motion for a new trial is much broader than its power to grant a JMOL." *Jennings v. Jones*, 587 F.3d 430, 436 (1st Cir. 2009). As Centocor concedes, a new trial may be granted even where the verdict is supported by substantial evidence, but is against the law or is tantamount to a miscarriage of justice. (*See* Centocor Opp. at 2 (citing *Crowe v. Marchand*, 506 F.3d 13, 19 (1st Cir. 2007)); *see also Jennings*, 587 F.3d at 439.) Here, not only is the verdict against the clear weight of the evidence, but it also contradicts the law on written description, enablement, and obviousness. (*See* Abbott's Renewed Mot. for Judgment as a Matter of Law and Supporting Mem. ("JMOL

Motion"); Abbott's Reply In Support of JMOL Motion ("JMOL Reply").) Accordingly, if the Court does not grant Abbott's JMOL Motion, it should grant a new trial.

# B. There Was Improper Introduction of Irrelevant Evidence and Argument Concerning Stelara

Centocor is wrong in its assertion that the introduction of Stelara evidence was directly relevant to its defenses. Evidence concerning Stelara's structure is irrelevant to the issues of written description and enablement because (i) Abbott's patent was not required to describe or enable Stelara or any other particular antibody and (ii) Abbott's asserted claims do not include any of the structural features by which Centocor sought to distinguish Stelara from the claimed invention. All that the law requires to support Abbott's claims is the disclosure of a representative number of antibodies that perform the function claimed, irrespective of their structure. (See JMOL Motion at 3-10; JMOL Reply at 2-6; see, e.g., In re Wallach, 378 F.3d 1330, 1334 (Fed. Cir. 2004) ("Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces."); Regents of the Univ. of California v. Dako N. Am., Inc., No. 05-3955, 2009 WL 1083446, at \*10 (N.D. Cal. Apr. 22, 2009) ("Plaintiffs are not required to describe a high number of species of the genus method because the '841 patent, and the prior art cited therein, describes little variation within the salient characteristics of that genus."). (emphasis added).)

Centocor's attempt to focus the jury on the structural differences between Stelara and Abbott's disclosed antibodies – and to suggest that Stelara's "side" binding is somehow preferential to Abbott's "bottom" binding – was a red herring that improperly distracted the jury from performing the proper functional analysis under the representative species test.

Moreover, even if the structure of Stelara had some relevance to the issues, the record does not support Centocor's assertion that it compared Stelara to all the disclosed embodiments, and not just to J695. While Centocor points to Dr. Eck's testimony "that he expected that all Joe 9 antibodies would bind the same as J695" and to Dr. Siegel's testimony that the amino acid sequences of the Joe 9 antibodies "were no more than 10% different from J695" (Centocor Opp. at 5), it ignores the undisputed evidence that even one amino acid change – let alone a 10% change – has an entirely unpredictable effect on an antibody's properties. (Tr. Day 5 at 25:13-16, 113:13-114:6, 119:10-123:5, 126:14-127:7 (Siegel); Tr. Day 9 at 11:4-12:5, 59:12-61:24 (Marks).) Indeed, the record evidence established that the Joe 9 antibody itself does not fall within the scope of Abbott's patent claims. (Tr. Day 5 at 140:23-141:2 (Siegel); Tr. Day 9 at 73:18-74:7, 82:10-84:8, 84:24-85:22, 87:2-22, 100:24-101:16 (Marks).) Therefore, Dr. Eck's unsubstantiated "expectation" about what other "Joe 9 antibodies" with varying amino acid sequences would do is not substantial evidence of how Stelara compares to Abbott's other disclosed embodiments. Rather, the only comparisons of structural binding to IL-12 that Centocor made were of Stelara and J695. (Tr. Day 3 at 140:8-23, 147:7-149:3, 154:13-161:7 (Eck comparing binding sites and structure of Stelara and J695).)<sup>1</sup> Such a comparison to one disclosed embodiment is legally improper. Cf. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1328 (Fed. Cir. 2003) (vacating and remanding noninfringement finding because trial court erred in comparing the process of the accused product to the process of an embodiment of the patent rather than the limitations of the asserted claims).

135:20 (Siegel); JMOL Motion at 11.)

To the extent that Dr. Siegel testified that none of the disclosed Joe 9 antibodies has the VH5 heavy chain and kappa light chain that Stelara does (Centocor Opp. at 6), this was nothing more than a repackaging of the fact that Stelara has a different structure (*i.e.*, amino acid sequence) than the Joe 9 antibodies. (*See* Tr. Day 5 at 134:24-

Additionally, Centocor is mistaken in asserting that it never abandoned its anticipation defense, and that, therefore, evidence concerning Stelara's independent development was relevant. (Centocor Opp. at 6.) Centocor dropped its anticipation defense for the three asserted non-composition claims at the conclusion of the evidence. (Id.) While Centocor asked the jury to decide anticipation for the remaining two composition claims, it did so based on its incorrect view of the law of inventorship that was repeatedly rejected by the Court and contradicted by the instruction on anticipation given to the jury. (Tr. Day 10 at 10-12; D.I. 341, Am. Mem. & Order on Cross-Motions for Summary Judgment at 62; D.I. 340, Mem. and Order on Mot. for Reconsideration at 12-13; Weiner 11/9/12 Decl. Ex. 1, Jury Instructions at 41 ("Additional inventors may make contributions after the date a species is invented that entitle the inventors to a genus patent claim, but those contributions are not relevant to the date of invention of the genus claim.").) Centocor's continued illegitimate pursuit of an anticipation defense that had no basis in fact or law cannot be used to justify the admission of irrelevant and prejudicial evidence. Centocor's recounting of Stelara's invention story was completely irrelevant to any issues that the jury was actually required to decide.

- C. Abbott Was Erroneously Precluded From Examining Witnesses Concerning the Prosecution of the Patents-In-Suit
  - 1. The Record Left an Incorrect Impression Regarding the Prosecution of the Patents-In-Suit

Centocor contends that "neither the Court nor any party ever suggested or stated to the jury that Centocor was absent from all proceedings before the Patent Office concerning the patents-in-suit." (Centocor Opp. at 7.) But this is precisely what was suggested to the jury through the combination of the patent video, Centocor's opening statement, and the Court's *i4i* instruction, all of which reinforced the inaccurate notion that Abbott's patents were granted "in private, without input from people who might later be accused of infringement." (Weiner

11/9/12 Decl. Ex. 8, Patent Video at 7; *see* Abbott's Corrected Mot. for a New Trial and Supporting Mem. ("Motion for New Trial") at 7-11.)<sup>2</sup> Although Centocor suggests that the Court's statement that the video does not "fit perfectly with this case" mitigated any misimpression (Centocor Opp. at 8), such a limited instruction, when dealing with the complex subject matter of patent prosecution unfamiliar to ordinary jurors, neither addressed nor corrected the suggestion that Centocor never had an opportunity to present to the Patent Office *any* of the evidence it presented at trial.

Centocor's assertion that it did not have an opportunity to provide the crystal structure of J695 to the Board is of no consequence.<sup>3</sup> First, as discussed *supra* on page 2, such evidence regarding structure was and is irrelevant to the invalidity issues before the Patent Office and the jury. Although at trial Centocor pointed to J695's VH3 heavy chain and lambda light chain as two additional structural features that differed from Stelara's, both Centocor and the Patent Office knew that Abbott's disclosed antibodies had these features long before this litigation, because this information is disclosed in the '128 Patent. (*See* Trial Ex. 1, '128 Patent at col. 41:1-8; 42:13-21 (VH3), 41:63-42:7 (lambda).) The Patent Office did not think this was an issue when it granted the asserted genus claims.<sup>4</sup> And Centocor had every opportunity to raise this as an issue during the interference, but it chose not to. Nevertheless, the jury was left with the

<sup>&</sup>lt;sup>2</sup> Centocor cites several cases for the proposition that district courts routinely show the patent video as part of a patent jury trial. (*See* Centocor Opp. at 7 n.4.) None of these cases involved a prior proceeding before the Patent Office in which the alleged infringer had the opportunity to present evidence of invalidity to the Patent Office.

Centocor's is wrong in suggesting that Abbott's counsel conceded the correctness of Centocor's statement that it would "present evidence the patent office did not have and could not consider when it issued patents." (Centocor Opp. at 8 n. 5.) Abbott's counsel actually stated that this portion of Centocor's opening statement was "precisely technically perhaps correct but not correct in the context of what we're dealing with." (Tr. Day 3 at 7:13-17 (emphasis added).)

While the Patent Office did not have the structural information relating to Stelara during the original prosecution of the '128 and '485 patents, the examiners were certainly aware that J695 contains specific types of heavy and light chains.

incorrect impression that Centocor never had an opportunity to submit its evidence to (and that Abbott purposely withheld it from) the Patent Office.<sup>5</sup>

Centocor's assertion that evidence of the interference would have been "improper, misleading, and confusing" (Centocor Opp. at 11) is also incorrect. First, while Centocor contends that there was evidence it could not have presented during the interference (namely, J695's crystal structure), it does not explain how this fact would have made it improper, misleading or confusing for the jury to have been told that an interference proceeding took place during which Centocor did have the opportunity to present *other* evidence to the Patent Office. Second, contrary to Centocor's assertion, Abbott never suggested in its opening brief that if the jury had been told of the interference, Abbott would have "argue[d] or even impl[ied] to the jury" that Centocor avoided certain defenses in the interference because it recognized them to be immaterial and weak. (Id. at 11.) Rather, Abbott noted that such an inference would have been a reasonable one for the jury to draw on its own based on this evidence. (Motion for New Trial at 10.) Finally, Centocor's contention that evidence of the interference would have been prejudicial and confusing because the interference involved only one of the two asserted patents does not withstand scrutiny. While the interference involved only the '128 patent, the '128 and '485 patents have a common specification, and Centocor never distinguished between the two patents when making its invalidity arguments at trial. Therefore, this fact would have in no way made the introduction of the interference prejudicial or confusing, and Centocor provides no reasoned explanation to the contrary.

<sup>.</sup> 

Additionally, whether or not Centocor could have provided J695's crystal structure to the Board does not change the fact that Centocor had the opportunity to provide the Patent Office with *every other* piece of evidence presented at trial, including evidence of the other structural differences between Abbott's J695 and Stelara, and every "new" prior art reference Centocor relied upon at trial. In fact, all of Centocor's "new" prior art references at trial were not materially different from the references it *did* provide to the Board. (*See* Abbott's Opp. to Centocor's Mem. in Support of Judgment on the Issue of Obviousness at 16-19, C.A. No. 4:10-CV-40003, D.I. 68.) Therefore, regardless of the crystal structure evidence, it was misleading to leave the jury with the impression that Abbott's patents were granted as part of an ex parte proceeding, without any opportunity for Centocor to provide *any* input or evidence.

Centocor ignores the cases Abbott cites in its opening brief in support of the proposition that fact finders in district court litigation routinely consider the initial patent examination and reissuance because it is directly relevant to the weight of the evidence. (*See* Motion for New Trial at 10 n.6.) Centocor attempts to justify its erroneous position by pointing to several cases in which district courts precluded evidence regarding post-issuance proceedings. (*See* Centocor Opp. at 9-10.) However, these cases are easily distinguishable. In the principal case on which Centocor relies, *Callaway Golf Co. v. Acushnet Co.*, the defendant sought to introduce to the jury evidence of a parallel, ongoing inter partes re-examination proceeding of the asserted patents. 576 F.3d 1331, 1342-43 (Fed. Cir. 2009). While claims had been rejected in that reexamination, the Patent Office had not completed the reexamination and therefore had not arrived at a final determination of the issue. *Id.* Here, in contrast, the interference was completed well before trial and resulted in a judgment for Abbott and against Centocor, which was final in the Patent Office.

In two other cases Centocor cites, *IA Labs CA, LLC v. Nintendo Co.*, 857 F. Supp. 2d 550, 552 (D. Md. 2012) and *CardioVention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 843 (D. Minn. 2007), interim reexamination determinations still under review in the Patent Office were, likewise, at issue. And in *Amphenol T&M Antennas, Inc. v. Centurion Int'l, Inc.*, No. 00 C4298, 2002 U.S. Dist. LEXIS 822, at \*2, 5 (N.D. Ill. Jan. 17, 2002) (Verrecchio 12/21/12 Decl. Ex. 7), there had not even been an interim decision by the Patent Office, but simply the decision to grant a reexamination proceeding. None of these cases involved a decision that had reached finality in the Patent Office like the interference decisions here. And in the one case Centocor cites involving an interference decision, *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374, 1380 (Fed. Cir. 1998), the interference at issue was brought by a third, unrelated party, not by the defendant who sought to introduce the interference decision. *Id.* at 1380. The

Federal Circuit affirmed the district court's preclusion of the interference decision in that particular circumstance because it "could conflate factual inquiries" by requiring the jury to compare the defendant's infringing product with the third party's unrelated patent. *Id.* at 1380-81. This is completely inapposite to the facts at issue here.

# 2. Abbott Was Improperly Foreclosed From Presenting Evidence Regarding the Non-Interference Prosecution History

Centocor appears to agree that Abbott was foreclosed from introducing evidence of arguments and specific issues considered by the Patent Office, but it incorrectly asserts that this was of no import. Centocor acknowledges that while the Court permitted testimony regarding the relevance (or lack thereof) of the evidence Centocor presented to the jury, the Court was explicit that it had "excluded evidence in this trial of arguments that were made to the PTO and the reasoning that the PTO used to make its decision." (Tr. Day 10 at 5:13-15; *see* Centocor Opp. at 15):

[A]rgument 1 is a factual or scientific argument. The crystal structure is trivial, it's unimportant, it would have made no difference to anyone. Argument 2 is this is what happened during the interference proceeding or the patent prosecution, and here's what argument were made, and here's how the patent office came out.... I don't want to let you have argument 2 for the reasons that I've described.

(Sept. 21, 2012 Preliminary Jury Charge Conference Tr. at 50:20-51:2.) Indeed, with respect to Dr. Siegel's cross-examination, the Court ultimately decided that it would not permit questioning regarding "what arguments [the Patent Office] found credible." (Tr. Day 6 at 21:17-25.)

Centocor misses the point as to the reason that this Court's ruling was erroneous and prejudicial. The ruling prevented Abbott from demonstrating to the jury that Centocor's structure-based written description and enablement arguments and its obviousness argument regarding the predictability of phage display technology had already largely been considered by the Patent Office. (*See* Motion for New Trial at 12-13.) Without delving into the specific issues

considered by the Patent Office – beyond just the general issues of written description, enablement, and obviousness, and beyond just asking witnesses about the overall relevance of Centocor's evidence to these issues – Abbott had no way of eliciting such information. Yet, such information was relevant to the jury's deliberations in light of the Court's *i4i* instruction, which applied to all "additional information," and not just prior art. (Weiner 11/9/12 Decl. Ex. 1, Jury Instructions at 25.)

Centocor also argues that Abbott was precluded from questioning Dr. Marks about the file history because Dr. Marks never considered the issue in his expert report, but this misstates both the report and the Court's ruling. (Centocor Opp. at 16.) Dr. Marks did, in fact, address in his expert report the arguments made before the Patent Office and its reasoning in accepting or rejecting them. (Weiner 11/9/12 Decl. Ex. 9, Marks Rebuttal Rep. ¶ 221 (discussing how Abbott overcame Patent Office's written description and enablement rejection); *id.* ¶¶ 225-26 (explaining Board's reasoning in rejecting Centocor's obviousness arguments); Tr. Day 8 at 176:5-8 (Mr. Lee: "But this is Paragraph 223 of his report where he specifically addressed the interference.").) The Court precluded Abbott from questioning Dr. Marks on the specific issues considered by the Patent Office not because they were not discussed in his report, but because it determined that the jury need not know what specific arguments the Patent Office accepted or rejected:

Mr. Lee: My question was going to be, "Did the Board consider the issue of obviousness in phage display?" His answer would have been "Yes," and the answer would have been, did the patent issue?

The Court: I don't see how that's required by i4i. I mean, in fact, I'm not sure that anything is required other than the patent was issued.

. . .

Mr. Lee: For written description and enablement, it's going to be what the Patent Office did during the prosecution. That was my second question. Am I not allowed to get into that either?

The Court: If the only case you have saying that you can get into it is i4i, I don't think it requires that, and I have real concerns about it. Again, the whole proceeding is a waste of time if we're just going to go through all the Patent Board's reasoning, you know, everything they considered, and all the jury is supposed to do is rubber-stamp that."

(Tr. Day 8 at 177:17-23, 178:24-179:8.)

Centocor does not even address any of the cases cited in Abbott's opening brief in support of the proposition that courts routinely permit juries to hear testimony about the arguments and evidence presented to the Patent Office because it is directly relevant to whether a patent is valid and infringed. (See Motion for New Trial at 15.) Instead, it seeks to rely on two cases for the proposition that numerous courts have precluded expert testimony on the prosecution history to avoid encouraging the jury "to rubber-stamp the decision of the Patent Office." (Centocor Opp. at 14.) The first case, Mycogen Corp. v. Monsanto Co., No. 1:04-cv-00573, 2005 U.S. Dist. LEXIS 19375, at \*47 (S.D. Ind. Aug. 11, 2005) (Verrecchio 12/21/12 Decl. Ex. 9), involved a non-jury trial in a Section 146 action. There, the court granted a motion to exclude the testimony of a patent attorney whose expert report amounted "to legal arguments and conclusions that merely echo Monsanto's briefs and/or address questions of law for this court to determine." Id. This is very different than the situation here, where Abbott sought to elicit expert testimony on specific issues already considered by the Patent Office, to demonstrate to the jury that much of the evidence and arguments Centocor attempted to present to the jury as new had, in fact, already been considered by the Patent Office.

Centocor's other case, *Minemyer v. B-Roc Representatives, Inc.*, No. 07 C 1763, 2012 U.S. Dist. LEXIS 12808, at \*12 (N.D. III. Feb. 2, 2012) (Verrecchio 12/21/12 Decl. Ex. 10), related to the issue of willful infringement. There, the defendant sought to introduce evidence of

23 events occurring before the Patent Office to show that "there are legitimate noninfringement arguments and credible invalidity arguments" for the asserted claims. *Id.* at \*4-10. The court concluded that this evidence was irrelevant to the issue of willful infringement, reasoning that interim office actions are "so commonplace that they hardly justify a good faith belief in the invalidity of the claims." *Id.* at \*12. Here, of course, Abbott did not seek to introduce evidence of the limited specific issues considered by the Patent Office in order to suggest patent invalidity. Rather it did so to show that these issues had already been considered by the Patent Office.

### D. The Court's *i4i* Instruction Was Erroneous

Centocor argues that Abbott's position with respect to the Court's *i4i* instruction is wrong because *i4i* requires an evaluation of whether evidence is "materially new" rather than "more material." (Centocor Opp. at 18.) Centocor attempts to confuse the issue with semantics.

Whether one refers to the evidence as "materially new" or "more material" is beside the point.

The specific problem is that the jury was never instructed to assess whether certain purportedly new evidence Centocor presented at trial may have been cumulative and no more relevant – or no more material – than the evidence already considered and rejected by the Patent Office.

Instead, the jury was simply instructed to consider whether that evidence would have been "material" to the Patent Office's decision to grant the patents, such that "a reasonable patent examiner would consider it important in deciding whether to allow the application to issue as a patent." (Weiner 11/9/12 Decl. Ex. 1, Jury Instructions at 25.) Because the Court failed to instruct the jury to consider whether Centocor's purportedly new evidence was materially new and not cumulative of what the Patent Office had already considered, the jury completely bypassed this critical step in the *i4i* analysis.

Likewise, Centocor misconstrues *American Hoist*. Centocor argues that while "*American Hoist* states that the clear and convincing standard 'may' more easily be met when the non-

considered art is more pertinent than the cited art" it does not hold that "the non-considered art must be more material than the considered art in order for the jury to consider giving it more weight." (Centocor Opp. at 19 (emphasis in original).) To the contrary, this is precisely what Amercian Hoist holds in stating that the challenger's burden "may more easily be met when the non-considered art is more pertinent than the cited art." Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1459 (Fed. Cir. 1984) (internal citation omitted)). In other words, the non-considered art must be more pertinent than the cited art before the burden may more easily be met.

Finally, Centocor argues that "Abbott provides no legal support" for its proposition that it was Centocor's burden to prove materiality and that the jury should have been instructed of the same. (Centocor Opp. at 20.) However, as Abbott pointed out in its opening brief (Motion for New Trial at 20), *American Hoist*, which has never been overruled, states this explicitly. 730 F.2d at 1459-60 ("[T]he burden is on the challenger to show that 'that prior art had not been considered.' The challenger meets that particular burden by showing that the uncited art is more relevant than that cited . . . ." (internal citation omitted)). Centocor fails to cite a single case to support its assertion to the contrary.<sup>6</sup>

### E. The Near Simultaneous Invention Instruction Was Improper

Centocor contends that because obviousness is evaluated as of the filing date of a patent, the fact that Centocor developed its invention prior to the filing date of Abbott's patents makes its invention nearly "simultaneous" and therefore relevant as a secondary consideration of obviousness. (Centocor Opp. at 22.) This makes no sense. The question of whether a

Centocor also makes the unsupported assertion that even if there were error in any aspect of the Court's *i4i* instruction, "Abbott cannot show any meaningful prejudice resulting from a review of the trial record as a whole." (Centocor Opp. at 19 n.9.) However, Abbott detailed the prejudice that resulted from this erroneous instruction and the record as a whole in its opening brief. (Motion for New Trial at 6-7, 10-11, 16-17, 21-23, 25-26, 28.)

simultaneous invention suggests obviousness can only be relevant if it occurred around the same time as the actual invention, not a later filing date, as it is the date of the actual invention against which most categories of prior art are judged. *See In re Farrenkopf*, 713 F.2d 714, 720 (Fed. Cir. 1983) (near-simultaneous invention shows that someone was "*motivated by* the prior art teachings to invent a method corresponding to the claimed invention") (emphasis added)). Thus, in determining whether near simultaneous invention exists, courts consider both the actual date of invention in terms of conception and reduction to practice, as well as the filing date. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 n.4 (Fed. Cir. 1986) (no simultaneous invention disclosed in publications and patent applications dated more than a year after the filing date of the patent in issue, and roughly two years after conception occurred); *Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1306 (Fed. Cir. 2010) (assessing simultaneous invention based on reduction-to-practice date).

Centocor itself concedes that it did not recognize that the Stelara antibody was neutralizing and had high affinity until October 1998 (Centocor Opp. at 22) – *two years* after Abbott's October 1996 reduction to practice for Abbott's non-composition claims ('128 patent claims 29, 30, and 32). (*See* Motion for New Trial at 24 (citing Weiner 11/9/12 Decl. Ex. 10, PDX 3-1).)<sup>7</sup> While Centocor points to the reduction to practice dates of Abbott's two composition claims – October 1997 for claim 11 of the '485 patent and February 1998 for claim 64 of the '128 patent – as evidence that Stelara was developed within Abbott's reduction to

Although Centocor contends that its scientists understood the Stelara antibody to be neutralizing (but not high affinity) by November 1997 (Centocor Opp. at 22), Ms. Giles-Komar's testimony demonstrates that even this was not appreciated by Centocor until February 2, 1998:

Q. So sometime before February 2, 1998, you decided that someone needed to repeat Mr. Kamperstein's [sic] experiments if you really were going to know whether the antibody was neutralizing, correct?

A. That's correct.

<sup>(</sup>Tr. Day 3 at 100:7-11.)

practice date range, Stelara was not reduced to practice until well *after* these dates, in October 1998.

Finally, Centocor attempts to discount Abbott's argument that the near simultaneous invention instruction was especially misleading and prejudicial in light of the Court's rulings precluding Abbott from eliciting evidence concerning the interference. (Centocor Opp. at 23-24.) Centocor argues that the interference issue of "which party was first to make the invention of the 'count' was different from the obviousness question posed to the jury, which focused on the issued claims measured against the prior art at the time of the filing of Abbott's patent application." (*Id.*) But Centocor's focus on the Board's priority decision ignores its obviousness decision, which is exactly the claim-by-claim inquiry addressed by the jury. (*See* Weiner 11/9/12 Decl. Ex. 6, Board Op. at 16:5-11 (discussing Centocor's obviousness challenge to claims 1-15, 27-40, and 50-64 of the '128 patent, in light of various prior art references); *see also In re Roemer*, 258 F.3d 1303, 1307 (Fed. Cir. 2001) (Patent interference rules "limit determinations of patentability in an interference proceeding to the claims, not counts.").)

## F. The Court Erred in Admitting Post-Filing Evidence Related to Obviousness

Centocor contends that Trial Exhibits 1358 and 1360 were properly admitted, not as prior art, but for purposes of impeaching Dr. Davis's obviousness opinion. (Centocor Opp. at 24-26.) However, as Abbott explained in its opening brief, these exhibits should not have been admitted for purposes of impeachment because they discuss the state of the art after Abbott's March 1999 filing date and therefore say nothing about the credibility of Dr. Davis's opinion of obviousness about the *pre-filing* state of the art. (Motion for New Trial at 27-28.)

While Centocor attempts to paint Dr. Davis's testimony about the pre-filing state of the art as contradicting the statements made in these exhibits, it minimizes the fact that Ex. 1358, an Abgenix patent listing Dr. Davis as an inventor, was granted in 2004 and filed as a provisional

application nearly *three months* after Abbott's filing date and that Ex. 1360, an article listing Dr. Davis as an author, was published *nine months* after Abbott's patent was filed. Therefore, Centocor's comparison of the state of the art, as discussed in these post-filing-date references that bear Dr. Davis's name, to the state of the art prior to Abbott's filing date, as testified to by Dr. Davis, is an apples to oranges comparison that does not legitimize the admission of these exhibits for purposes of impeachment. Indeed, under Centocor's theory, as long as one can refer to a reference as dated "months" after the filing date cutoff for prior art (Centocor Opp. at 25) it is fair game for purposes of undermining a witness's obviousness opinion. That is an arbitrary and illogical position with no support in the law.

Finally, Centocor implies that because Abbott's counsel sought a clarifying instruction that these exhibits were not being offered for the truth of the matter, so as to not mislead the jury about their purpose, this somehow diminishes the prejudicial effect of the Court's ruling. (*See* Centocor Opp. at 27.) Yet, the Court's instruction went beyond discussing the truth of the matter and into how impeachment evidence is used to undermine a witness's credibility. (*See* Tr. Day 8 at 24:19-25:6.) Given that this impeachment instruction was given for the first time at trial during and in reference to Dr. Davis's examination, despite several prior instances of impeachment of other witnesses, the ruling was particularly prejudicial.

### III. CONCLUSION

For the reasons set forth above and in Abbott's Corrected Motion for a New Trial and Supporting Memorandum, Abbott respectfully requests that the Court grant a new trial in this matter.

## Respectfully submitted,

Dated: January 11, 2013

### /s/ Robert J. Gunther, Jr.

Robert J. Gunther, Jr. (admitted *pro hac vice*)
Jane M. Love (admitted *pro hac vice*)
Anne-Marie Yvon (admitted *pro hac vice*)
Violetta G. Watson (admitted *pro hac vice*)
Paula Estrada de Martin (admitted *pro hac vice*)
Barish Ozdamar (admitted *pro hac vice*)
WILMER CUTLER PICKERING
HALE and DORR LLP
7 World Trade Center

New York, New York 10007 Tel: (212) 230-8800 Fax: (212) 230-8888

William F. Lee (BBO #291960) Anne M. McLaughlin (BBO # 666081) WILMER CUTLER PICKERING HALE and DORR LLP 60 State Street Boston, Massachusetts 02109

Tel: (617) 526-6000 Fax: (617) 526-5000

William G. McElwain (BBO # 332510)

Amy K. Wigmore (admitted pro hac vice)

Amanda L. Major (admitted pro hac vice)

Jacob S. Oyloe (admitted pro hac vice)

Rachel L. Weiner (admitted pro hac vice)

WILMER CUTLER PICKERING

HALE and DORR LLP

1875 Pennsylvania Avenue, NW

Washington, DC 20006

Tel: (202) 663-6000

Fax: (202) 663-6363

William W. Kim (admitted *pro hac vice*) Arthur W. Coviello (BBO # 670152)

WILMER CUTLER PICKERING

HALE and DORR LLP

950 Page Mill Road

Palo Alto, California 94304

Tel: (650) 858-6000 Fax: (650) 858-6100 Attorneys for Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc., and Abbott Biotechnology, Ltd.

## CERTIFICATE OF SERVICE

I certify that, on January 11, 2013, this document (filed through the ECF system) will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

/s/ Robert J. Gunther, Jr. Robert J. Gunther, Jr.